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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/992,665

11/13/2001

Kaia Palm

CEMINES.002A

8494

24113

7590

05/30/2006

EXAMINER

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UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/992,665	PALM, KAIA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 3/17/06, 5/5/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 67-72, 75, 78-110, 135 and 136 is/are pending in the application.
- 4a) Of the above claim(s) 80, 82-95, 97-110, 135 and 136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 67-72, 75, 78, 79, 81 and 96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/17/05</u>                                                   | 6) <input type="checkbox"/> Other: _____                                    |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on November 15, 2005, Marcy 17, 2006 and May 5, 2006 are acknowledged and have been entered. Claims 73-74, 76-77, 111-134 have been canceled, claims 67, 70-71, 75, 78-80, 82-86, 88-90, 94-110 have been amended, new claims 135-136 have been added. Claims 82-95, 97-110 remain withdrawn from consideration and newly amended claim 80, and newly added claims 135-136 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. An action on the RCE follows
2. Claims 67-72, 75, 78-79, 81, 96 are pending and currently under examination.
3. It is noted that Applicant has elected the Invention of Group 37, which includes Group A/Claim 82 (which for the reasons of record has been withdrawn from consideration) and Group (d) which required the election of a single specific type of factor or a specific combination of the 43 specific types of factors recited in claim 96 (see page 20 of the Paper mailed September 10, 2004). Since Applicant elected the Hey/HRT family of proteins, those are the specifically elected combination of types of transcription factors that will be examined in this RCE if the generic claim is not found to be allowable. It is noted that claim 80 has been withdrawn from consideration because it requires that the plurality of the transcription factor types comprise at least four transcription factor types. Given Applicant's election of the combination of the Hey/Hrt family types of

transcription factors, given that at the time the invention was made only three members of the family were known as taught by Katoh et al (Int. J. Mol. Med, 2004, 14:747-751, p. 747, col 2), claim 80, drawn to at least four types of transcription factors types has been withdrawn from consideration. Further, claims 135-136 are withdrawn from consideration because they are not drawn to the elected Hey/Hrt family types of transcription factors.

4. It is noted that the amendment filed November 15, 2005 appears to contain an inadvertent typographical error wherein the term “factors” in claim 67 was amended to “factor” in the absence of any indicator that an amendment had been made. Given that it appears that the error was inadvertent, and in the interests of compact prosecution, examination of the claims will go forward, however, Applicant is required to correct this omission in response to this office action.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The following rejections are being maintained:

***Claim Rejections - 35 USC 112***

7. Claims 67-72, 75, 78-79, 81, 96 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed September 15, 2005, Section 4, pages 2-4.

It is noted that the specification as originally filed does not defined “types” of transcription factors, thus it is assumed for examination purposes that transcription factors that are chemically or functionally different, one from the other, even if they belong to the same transcription factor family, are different “types” of transcription factors.

In the paper submitted November 15, 2005 Applicant argues that the present amendment clarifies that what is claimed is testing from an autoimmune response against a plurality of transcription factors including a Hey/HRT factor to thereby determine from a result of the testing that the host has a cancer and to thereby further determine a type of the cancer and that this claim is enabled by showing that NSCLC could be determined by testing for all the factors shown in Table 11, including a Hey/HRT factor. Applicant further argues that HeyL/HRT3 is a good indicator, by itself for NSCLC but is not dispositive and the claimed technique does not rely on only one marker. The argument has been considered but has not been found persuasive because in the paper submitted December 10, 2004 Applicant specifically clarified that the election of Hey/HRT family is meant to include all members of the Hey/HRT family, that is the combination of the three known Hey/HRT types of transcription factors, and thus the fact that one of the members of the family is useful for detecting NSCLC, but not the others, is not enabling for the claimed invention for the reasons of record. In particular, the elected invention was examined and found not to be enabled wherein the specification as originally filed clearly demonstrated that the elected invention was not enabled. Although Applicant now states that the present amendment is drawn to a plurality of transcription factors including **a Hey/HRT** (emphasis added) factor, this is not what was previously elected and examined. It is noted that 35 U.S.C. 132(b) provides for continued examination of an application at the request of the applicant (request for continued examination or RCE) upon payment of a fee, without requiring the applicant to file a continuing application under 37 CFR 1.53(b). Applicants cannot file an RCE to obtain continued examination on the basis of claims that are independent and distinct from the claims previously

claimed and examined as a matter of right (i.e., applicant cannot switch inventions). See 37 CFR 1.145. It appears that Applicant is attempting to switch inventions to be examined by filing an RCE and as set forth above, this is not permitted. Since the claims as currently constituted read on the originally presented and examined invention, the claims are examined only to the extent that they read on the originally presented and examined invention.

In the paper submitted November 15, 2005 Applicant further argues that the Office Action has incorrectly taken the position that claim 67 is not enabled if the claim can be construed to read on one embodiment that is not enabled and points specifically to *Atlas Powder v Dupont* and states that even if some of the claimed combinations are inoperative, the claims are not necessarily invalid. The argument has been considered but has not been found persuasive because it is the elected invention that is not enabled for the reasons of record.

Further, in the paper submitted November 15, 2005 Applicant reiterates arguments drawn to restriction practice and points specifically to species restriction practice. The arguments have been considered previously and have not been found persuasive for the reasons of record. Examiner once again suggests that Applicant review MPEP 804.01 for further information on linking claim restriction practice.

Further, in the paper submitted November 15, 2005 Applicant argues that the Office did not show good reasons why the claims are not enabled. The argument has been considered but has not been found persuasive because Examiner clearly presented evidence from Applicant's own specification clearly demonstrating that the claimed invention is not enabled.

The arguments have been fully considered but have not been found persuasive and the rejection is maintained.

In the paper submitted May 5, 2006 Applicant requests a re-restriction in light of the clarified claims and provisionally elects a combination of transcription factor types different than the ones elected and previously examined. The request has been considered but is denied because Applicant cannot file an RCE in order to switch inventions for the reasons set forth above (also see 37 CFR 1.145). It is noted for Applicant's convenience that in the filing of a divisional or continuation application, upon restriction if necessary, examination of an invention different than the one examined in the parent application is permitted.

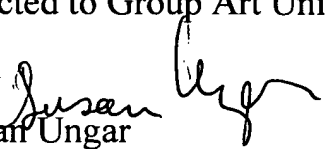
8. All other rejections set forth in the previous office action are hereby withdrawn.

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

  
Susan Ungar  
Primary Patent Examiner  
May 16, 2006